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Implementing a Communication and Analysis Solution for Risk Management

Food and Drug Administration

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Abstract

This document describes how SAS can help the FDA implement new communication and analysis tools for risk management associated with prescription drugs. Detailed within this document is information about technologies from SAS as they relate to FDA goals, our company, our implementation methodology, our work with the Department of Health and Human Services, and how we can work with you.

About SAS

SAS has been a contractor and a partner to government agencies since the company's inception 26 years ago. Driven by their need to meet missions and goals, federal, state, and local government agencies rely on SAS to turn vast volumes of data from any source and across every channel into usable knowledge.

Background

SAS wishes to form a partnership with FDA to help modernize the agency's traditional communication tools associated with risk management of prescription drugs. SAS understands that FDA performance plans include strategies to reduce preventable deaths and injuries associated with the use of medical products.

The goals of these plans are:

- to develop and enhance surveillance of FDA-regulated products
- to identify harm resulting from use, to understand harm through expert analysis
- to prevent harm to other patients by taking action.

Approximately 1.3 million people are accidentally injured by medical therapy in the U.S annually. Many errors are associated with the misuse of drugs and medical devices regulated by FDA. Costs from these medical errors range from $20 to $75 billion each year. The Institute of Medicine estimates that as many as 98,000 Americans die annually as a result of preventable medical errors.

For its part in attacking this problem, FDA is adopting a systems approach, of which the most significant component is the identification of, and response to, adverse events that are reported in the U.S. FDA is planning to expand its knowledge of adverse events and medical errors by linking with new sources of data.

Most injuries and deaths associated with medical products result from known side effects. Some side effects are unavoidable but others can be prevented or minimized by careful product choice and use. The greatest need is to identify potential threats and then educate patients and health care professionals to avoid them.

The FDA is responsible for reviewing reports, and, through careful investigation, research and additional information, should be able to determine the risk associated to public.

How SAS can help FDA realize its goals

SAS can help FDA achieve its goals by integrating and augmenting existing systematic initiatives through our best practice implementation methodology (as defined on pg. 6 of this document). SAS capabilities will integrate and augment the following technology initiatives currently in place.

Implementing a MedSun System, Linking with Existing Data Sources, Upgrading AERS and Continuing MedWatch

The SAS Intelligence Architecture will provide additional capabilities as FDA continues with the MedSun pilot program. SAS will augment the current Internet-based form that is being developed to report adverse medical events as part of the pilot program. In addition, SAS will provide the necessary methodologies and intelligence to further meet the goals outlined for a national surveillance system.

The proposed SAS capabilities will integrate with existing FDA data sources and external data sources. SAS capabilities also will augment the existing systems FDA systems currently in place. SAS capabilities and methodologies will enable FDA to bring together a comprehensive, 360-degree view of all your data in order to gain real knowledge. SAS accesses every major database and file structure available, utilizes the

most powerful data transformation language on the market, and integrates data quality monitoring and enrichment capabilities.
The SAS Intelligence Architecture integrates industry-leading SAS capabilities in data capture, analytical intelligence, data dissemination, data presentation and in facilitating the development of key performance indicators to communicate results. Within this framework, SAS' Intelligence Architecture provides the capabilities needed by FDA to design a national surveillance network:

- **Rules based data collection.** As data is uploaded by the participating medical institution, it is validated in real-time against the FDA-defined business rules. The institution is immediately alerted to any problems with their data by a detailed exception report. Business rules are easily maintained by non-programmers via a web-based point-and-click GUI. FDA business analysts will have the ability to monitor and augment rules and build additional data collection templates as needed.
- **Edit, modify and delete data after it has been submitted.** Once uploaded and accepted by the system, institutions will have the ability to view summary reports and make online record changes.
- **Easily implement on-line forms.** The SAS Web-Form Designer is a suite of browser-based tools that provide capabilities for easily creating and managing data collection instruments (web-forms) securely over the web. At the core of the tool set is a survey writing engine driven by a simple model of databases containing survey and question metadata. Data collection forms can literally be created in minutes instead of days. Any modifications made to a question will be reflected automatically in all references to that question. Supporting backend databases are created automatically to capture and store the user responses to the form input fields (questions). Survey database documentation is created and maintained automatically.
- **Transfer data and provide access to reports in a secure environment.** Given the sensitivity of the data required for adverse events incident reporting data, SAS solutions offer extensive security features that control access to the different system components. The security system has multiple levels

of access, supports group management and logging, and has encryption of passwords—all within a friendly user-interface.

- **Logging of web activity to monitor usage.** The security module tracks who has logged in, the host IP address, date/time of attempted login, and failed login attempts, as well as other factors. A portfolio of reports is available to the administrator to display detail data and trending.
- **Automated e-mail alerts to FDA and users.** Prior to the end of a reporting period, non-contributing institutions will be notified of their account status and asked to provide any missing information. E-mail alerts are driven dynamically by database activity which provides easy automation of a potentially time consuming and tedious communication task.
- **Institution/FDA data lockout and management tools.** After reviewing data for accuracy, medical institutions can lock down their data, signaling to the FDA that it has been reviewed and is ready for inclusion in the aggregate results. The FDA administrator can view, from a single screen, the current status of data submission across all medical institutions. After the data submission deadline has passed, the FDA administrator can initiate an enterprise lock-out procedure which prevents any further modifications to the data.
- **On-line help will assist users in reporting their information.** This SAS capability will guide users throughout the system. On-line help will aid emergency rooms, poison control centers, health care systems, and the Centers for Disease Control and Prevention (CDC) as they collect information on adverse reactions.

Using SAS solutions, the FDA will have the capability to communicate critical performance indicators to stakeholders based on a strategic analysis of adverse events reported. The aggregated information could include key performance indicators such as number of months the drug has been on the market, types of complications, fatal versus non-fatal incidences, jurisdiction location of hospitalization, and/or various institutions that reported the data elements.

Analysis and Response

SAS offers true analytical capabilities, including predictive and descriptive modeling, forecasting, simulation and optimization, allowing for problem-solving and intelligent decision-making. SAS data mining technology will help FDA to recognize patterns, associations, and what is commonly referred to as "signal detection," in data from the adverse event reporting systems database. If patterns are strong, this may be an indication of a syndrome and provide a timely method for uncovering areas that requires further study. Various methods of clustering can be utilized to build, compare and discover patterns that exist in the data as well. These patterns are not easily discernible with other methods of analysis such as on-line analytical processing (OLAP), cross-tabulation or frequency counts.

Data mining techniques can also involve predictive analysis for further understanding of how side effects can be accurately predicted by various other drug effects. Regression analysis, decision trees and neural networks are often employed as predictive or exploratory methods for performing such analyses. Using these techniques as a means of exploratory analysis, in conjunction with data visualization, provides a powerful means for uncovering relationships in the adverse reporting database that would otherwise go unnoticed.

Coupled with data mining is SAS' text mining technology. Using this technology, FDA will be able to sort through large volumes of textual data to uncover underlying themes or concepts. SAS Text Miner solves the problem of too much unstructured, text-based data piling up in organizations. With SAS Text Miner, FDA will be able to apply analytics to discover unseen patterns and unearth intelligence otherwise buried in these collections of free-form text.

SAS Implementation Methodology

The SAS implementation methodology consists of a series of pilots utilized to build and implement tools to manage risk and better address the efficacy of specific drugs. SAS recommends a services-based contract consisting of several pilot implementations, training and documentation. Experience has proven that the pilot methodology works because it provides a proof-of-concept before expending the resources to

launch a full-scale implementation. The pilot program is a step-by-step process that will allow for:

- the development of the requirements for the web capabilities needed for medical institutions to enter adverse effects
- the development of the database that will be utilized by FDA to analyze patterns
- the ability to identify key performance indicators to communicate the current status of adverse effects

The SAS engineering team will work with the FDA staff to gain a common understanding of the critical requirements for the development of this database. The statement of work will incorporate a plan to establish successive milestones so success is seen early and often. Since each milestone validates the project scope, our plan must be flexible, allowing us to adjust quickly and easily as results are demonstrated.

SAS Success with the U.S. Department of Health and Human Services

The success of SAS and HHS' long-standing relationship is evidenced by the success of our customers. Here are a few examples of how HHS is using SAS to accomplish their missions and goals:

Indian Health Services

An agency of the U.S. Department of Health and Human Services, the IHS is responsible for providing federal health services to American Indians and Native Alaskans. Using SAS, the agency developed the Indian Health Performance Evaluation System (IHPES).

The IHS turned to SAS in response to new hospital accreditation standards set by the Joint Commission on the Accreditation of Healthcare Organizations. Both groups want to improve performance and set standards to ensure that hospitals provide the best possible care. "Being able to centralize the clinical data collected at a national level has helped IHS rapidly and more accurately elevate the health status of

American Indians and Native Alaska populations," says Mike Gomez, IHPES program manager.

To meet accreditation standards, the IHS turned to the private sector for solutions. What the agency found, however, were costly options that would require additional staffing and fell short of meeting the unique medical needs of the American Indian and native Alaskan populations.

The agency turned to its existing infrastructure for support in developing a system that would satisfy the new requirements while maximizing return on investment from existing systems. The result: 42 of 49 existing agency hospitals use the IHPES and several new hospitals are scheduled to begin participating.

Using SAS, the IHS customized existing operations to consolidate data from across the United States and centralize it in a national database. The agency can now compare actual performance to the accreditation standards to measure success at each hospital, and hospitals can use the IHPES information to adjust procedures to better meet patient needs.

National Center for Injury Prevention and Control, Centers for Disease Control (CDC)

The Centers for Disease Control and Prevention (CDC) began studying home and recreational injuries in the early 1970s and violence prevention in 1983. From these early activities grew a national program to reduce injury, disability, death, and costs associated with injuries outside the workplace. In June 1992, CDC established the National Center for Injury Prevention and Control (NCIPC). As the lead federal agency for injury prevention, NCIPC works closely with other federal agencies; national, state, and local organizations; state and local health departments; and research institutions. The NCIPC works to reduce morbidity, disability, mortality, and costs associated with injuries.

The Office of Statistics and Programming within the NCIPC receives hundreds of requests per year for information on injury-related mortality data. Calls from public health researchers, journalists, legislators and others come in daily requesting very varied, often complex data. The NCIPC had a static Web site with very basic information, but the site lacked interactivity, customization and did not include everything. Therefore, the staff spent most of their time processing requests.

According to Steve James, Computer Specialist, it was a "no brainer" to develop an interactive, Web application using SAS/IntrNet. "We would have had to have a very good reason to use something other than SAS," Steve said. A year later WISQARS™ (Web-based Injury Statistics Query and Reporting System) was born. WISQARS is an interactive system that provides customized injury-related mortality data useful for research and for making informed public health decisions.

Using SAS/IntrNet, WISQARS allows anyone to create his or her own customized reports. For example, Injury Mortality Reports determine injury deaths and death rates for specific external causes of injuries, and Leading Causes of Death Reports determine the number of injury-related deaths relative to the number of other leading causes of death in the United States or in individual states. Because it is available on the public Internet, NCIPC was able to extend SAS' powerful data retrieval and analysis functionality to everyone.

"In addition to the benefit of saving time for the staff, there is the benefit that more people have access to this system," Steve said. Steve also said it has made his job easier and he is having much more fun "maintaining the application that does something rather than doing the something."

Since this site went live in March 2000, the requests directly to the staff for information have dropped significantly. However, the amount of requests and report generation directly on the site is increasing tremendously. Although not all have come in the form of research requests, there have been 8,000 hits to the site in the three weeks it has been live. That is more requests than the NCIPC would have received in years!

The site is available at http:// www.cdc.gov/ncipc/wisqars

Summary

SAS can help the FDA save thousands of lives and billions of dollars by implementing a communication and analysis solution for risk management that meets your strategic goals. SAS solutions are ideally suited to identify, analyze and prevent adverse events. SAS understands the FDA's desired outcomes and, through our iterative implementation

methodology, can help ensure that those outcomes are met quickly and efficiently.

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